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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,424

07/05/2006

Jeff Chen

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63572

7590

05/23/2011

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EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

05/23/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,424	Applicant(s) CHEN ET AL.	
	Examiner SAMIRA JEAN-LOUIS	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/22/11.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 22-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 4-6 and 10-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/22/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

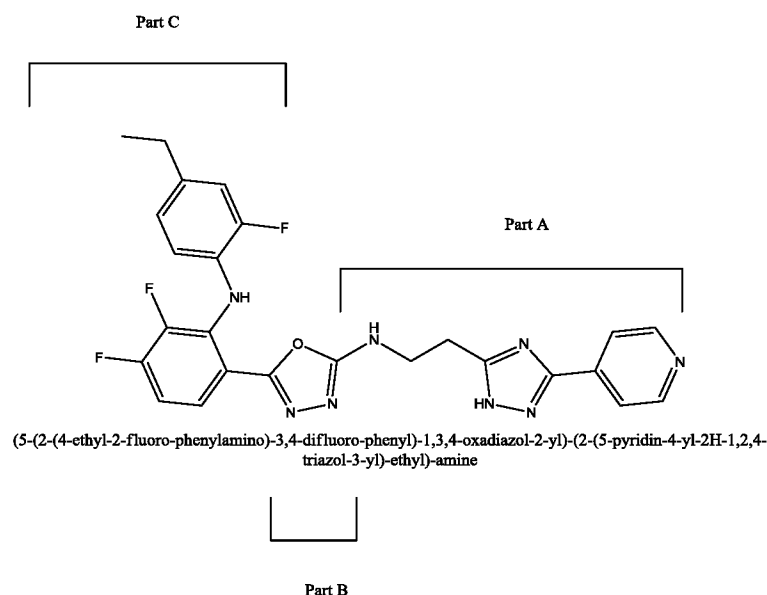
This Office Action is in response to the amendment submitted on 03/22/11. Claims 1-54 are currently pending in the application, with claims 22-54 having being withdrawn. Accordingly, claims 1-21 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the 112, first paragraph rejection over claims 1-21 for the treatment of all kinase-dependent disease or condition has been fully considered. Given that applicant has amended the claims to now recite the treatment of Tie-2 kinase dependent disease or condition, such rejection is now moot. Consequently, the rejection of claims 1-21 under 35 U.S.C. 112, first paragraph rejection is hereby withdrawn.

Applicant's argument with respect to the 112, first paragraph rejection over claims 1-21 for the hydrates and prodrugs of formula I has been fully considered. Given that applicant has amended the claims to now delete hydrates and prodrugs from the claims, such rejection is now moot. Consequently, the rejection of claims 1-21 under 35 U.S.C. 112, first paragraph rejection is hereby withdrawn.

Applicant's argument with respect to the 102(e) rejection over claims 1-3 has been fully considered. Applicant argues that the compounds of Biwersi et al. are not within the scope of the compounds of the recited claims. According to applicant, the atom in the 6-membered ring aromatic ring is a carbon in Biwersi while the instant claims require such atom to be nitrogen. Such arguments are however not found persuasive as the Examiner contends that Biwersi et al. does indeed anticipate independent claim 1. Attention is directed to compound 136 of Biwersi of the following structure:



which reads on instant compound of formula I. Specifically, part A of the compound of Biwersi reads on the instant 6-membered aromatic ring wherein Y are CH and m and n are 0. This aryl ring is attached to a 5-membered ring as denoted in instant compound of formula I wherein (counterclockwise) B and A are -N=; A is -C(H)=; and A is NH; L is a C2 alkylene group; X is NR₃ wherein R₃ is H; and Z represents part B above. According to independent claim 1, Z is R₄ or an optionally substituted heterocycle. Part

B represents 1,3,4-oxadiazole which is a heterocycle substituted by part C. Since there is no specific requirement for the substituents of R₄, the Examiner contends that compound 136 anticipates the instant compound of formula I. As a result, the Examiner contends that the 6-membered ring of Biwersi (i.e. part A) is in fact a heteroarylene and does indeed read on the instant compound of formula I. Thus, the rejection was indeed proper and is therefore maintained.

Applicant's argument with respect to the 103(a) rejection of claims 7-9 has been fully considered. However, such arguments are not found persuasive as the examiner contends that Biwersi did indeed anticipate instant compound of formula I. Moreover, the Examiner reiterates the fact that extension by one carbon chain is obvious to one skilled in the art and absent any unexpected results such compounds are homologs. Consequently, the Examiner maintains that the rejection was indeed proper and is therefore maintained.

For the foregoing reasons, the rejections of claims 1-21 under 35 U.S.C. 112, first paragraph are hereby withdrawn. However, the rejections under 102(e) and 103 (a) remain proper. In view of applicant's amendment, the following modified 102(e) and 103 (a) Final rejections are being made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

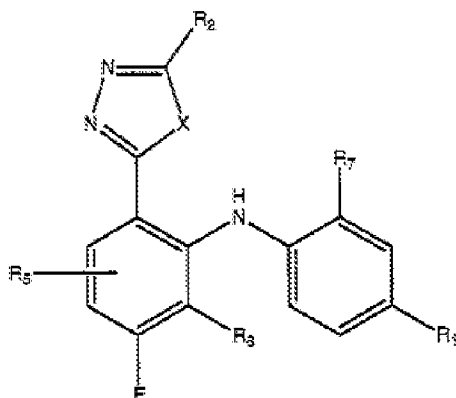
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by
Biwersi et al. (WO 2004/056789 A1, previously cited).**

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Biwersi et al. teach MEK inhibitors OXA- and THIA-Diazol-2-yl phenylamine compounds and derivatives and pharmaceutical compositions and methods for their use in proliferative diseases such as cancer (see abstract, pg. 2, lines 26-30, pg. 8, lines 31-33, pg. 9, lines 1-7, and pg. 100, lines 10-19). In particular, Biwersi et al. teach that MEK enzymes are dual specificity kinases involved in proliferative diseases such as cancer and that proliferative diseases are caused by a defect in the intracellular signaling system or the signal transduction mechanism of certain proteins (see pg. 1, lines 1-7). Additionally, Biwersi et al. teach compounds of the following structure:



or pharmaceutically acceptable salt or ester thereof (see pgs. 3-5). Specifically, compound 136 of Biwersi et al. read on instant compounds of formula (I) wherein all Y of instant compound of formula I are equal to =CH-; m and n are 0; counterclockwise, B and A are -N=; A is -C(H)= and A is NH; L is C₂ alkylene; X is NR₃ wherein R₃ is H; and Z is R₄ or a substituted heterocycle (wherein oxadiazole represents a substituted heterocycle) (see pg. 69, compound 136).

Accordingly, Biwersi et al. anticipate claims 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Biwersi et al. (WO 2004/056789 A1, previously cited).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The Biwersi et al. reference is as discussed above and incorporated by reference herein. However, Biwersi et al. do not teach R4 as an optionally substituted heteroaryl C1-C6 alkyl.

However, the Examiner contends that extension by one carbon chain (i.e. CH₂ heteroaryl) is obvious to one skilled in the art. Moreover, the Examiner contends that homologs are considered to be obvious absent unexpected results. In re Henze, 85 U.S.P.Q. 261, 263, (C.C.P.A. 1950).

A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and/or similar utilities. "An obviousness rejection based on

similarity in chemical structure and/or function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.” In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (discussed in more detail below) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to extend the carbon chain by one carbon since such extension is obvious and would have yielded similar results and given that such compounds are homologs of compound 136. Given the teachings of Biwersi et al., one of ordinary skill would have been motivated to formulate the compound of Biwersi et al. as a C1alkyl heteroaryl with the reasonable expectation of providing a method that is effective in treating proliferative diseases such as cancer.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/552,424
Art Unit: 1627

Page 10

/S. J. L./

Examiner, Art Unit 1627

05/17/2011

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627